II. Remarks

A. Status of Claims

Claims 1-24, 63 and 64 are pending in the subject application. By this amendment, Claims 1 and 5 have been amended to recite that the sealing element is slidably movable over the orifice of the fluid sample collection device. Support for the amendment may be found throughout the application, and particularly at FIGS. 18-19 and the corresponding text. No new matter has been added.

B. April 16, 2009 Examiner Interview

Applicants would like to thank Examiner Alexander for the personal interview conducted on April 16, 2009. In compliance with M.P.E.P. § 713.04, the substance of that interview is reflected in the April 21, 2009 Interview Summary and in the following remarks.

During the interview, Amendments to Claim 1 were discussed to indicate that the sealing element slides over the orifice of the cartridge. The Examiner agreed that such amendments appear to overcome Zelin, which teaches the sample application orifice external of the device as shown in FIG. 4. Applicants stated Davis et al. is commonly owned and will be excluded by a proper submission under 35 USC §103(c). Applicants additionally traversed the combination of Zelin in view of Yokota et al. as improper because the reference is non-analogous art.

Applicants acknowledge with appreciation the indication by the Examiner that the rejection over Zelin will be overcome with the aforementioned amendments and the application of Yokota et al. will be moot.

Finally, Applicants traversed the 35 USC §112, 1st paragraph, rejection stating paragraph [0072] of the published application teaches the closure of the device after the application of the blood sample and prior to insertion into the device and appears to obviate the 35 USC §112, 1st paragraph, rejection.

C. Rejections Under 35 U.S.C. § 112, first paragraph

Claims 1-24 and 63-64 stand rejected under 35 USC §112, first paragraph, as allegedly not complying with the written description requirement. Specifically, it was alleged that the original specification does not require the slidably moving sealing element to be placed over the

orifice prior to insertion into the reader as presently claimed. Applicants respectfully traverse this rejection.

As discussed in the Examiner Interview, paragraph [0072] of the published application clearly indicates with reference to FIGS. 18 and 19 that closure element 200 is manually actuated from the open to the closed position after blood has been added to the entry port and it enters the holding chamber 34, i.e., before insertion of the cartridge into the reader device. In addition, FIG. 18 clearly illustrates a cartridge having a closure member in the "closed" position, but prior to insertion into the reader device. From at least the foregoing description, Applicants submit that those skilled in the art would readily appreciate that the closure member should be manually closed prior to insertion into the reader device. The withdrawal of this rejection is respectfully requested.

D. Rejections Under 35 U.S.C. §103(a)

Claims 1-24 and 63-64 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,821,399 to Zelin in view of US Patent No. 5,846,490 to Yokota et al. In addition, Claims 1-24 and 63-64 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,419,821 to Davis et al. Applicants respectfully traverse these rejections.

1. Rejection over Zelin in view of Yokota

Claim 1 as amended recites a method of sealing a fluid sample collection device comprising "slidably moving a sealing element over the orifice of the fluid sample collection device prior to insertion into a reader and over at least a portion of said substantially planar surface in a way that [1] displaces any excess fluid sample away from the orifice, [2] seals the fluid sample within said holding chamber, and [3] inhibits the fluid sample from prematurely breaking through the internal capillary stop." Independent Claim 5 recites similar features. As agreed to during the interview, Zelin fails to teach slidably moving a sealing element over the orifice of the fluid collection device prior to insertion into a reader as claimed. Accordingly, independent Claims 1 and 5 are patentable over Zelin, and the allowance thereof is respectfully requested.

As discussed in the Examiner Interview, FIG. 4 of Zelin shows in cross-section a cartridge partially inserted into a reader device. As shown by the broken lines on the left side of FIG. 4, the protruding fluid collection portion, which is visible in the bottom left portion of FIG. 1, is not shown in FIG. 4. Based on the available room shown inside of the reader device in FIG. 4, however, one skilled in the art would readily appreciate that the fluid collection portion would protrude externally relative to the reader device even after the cartridge has been fully inserted into the reader device. As summarized by the Examiner in the April 21, 2009 interview summary, "Zelin . . . teaches the sample application orifice external of the device as shown in figure 4." For this reason, Applicants submit that the Office's assertion in the Office Action that "The insertion of the device (10) into the reader (150) performs the claimed function of '...displac[ing] any excess fluid sample away from the orifice, [and] seal[ing] the fluid sample within the holding chamber...'" is factually inaccurate. Applicants therefore maintain that Zelin does not teach or suggest a device in which a sealing element is slidably moved "over the orifice of the fluid sample collection device prior to insertion into a reader and over at least a portion of said substantially planar surface in a way that displaces any excess fluid sample away from the orifice, seals the fluid sample within said holding chamber, and inhibits the fluid sample from prematurely breaking through the internal capillary stop." This deficiency of Zelin is not remedied by any other reference of record.

In summary, Zelin simply does not disclose a sealing element that (1) displaces fluid, (2) seals the fluid sample in a holding chamber and (3) inhibits the fluid sample from prematurely breaking through a capillary stop. Indeed, the sample entry orifice of Zelin remains ***external*** to the reader of Zelin during the insertion process, and the act of inserting the Zelin device into a reader simply would have no impact on ***any one of*** displacing excess fluid, sealing fluid sample, or inhibiting the sample from prematurely breaking through a capillary stop. The Office's position that the insertion of the Zelin device performs any one of these functions—let alone all three—has no basis in the Zelin patent. For these reasons, the rejection based on Zelin is improper and should be withdrawn, and the allowance thereof is respectfully requested.

Additionally, as discussed in the Examiner Interview, Applicants respectfully assert that the combination of Zelin and Yakota is improper as Yakota is directed to a test device that is a simple strip design, as shown in FIG. 5 thereof. The device is an "open" device to the extent that sample is applied to an exposed pad attached to the strip exterior. Thus, Yakota has no direct relevance to the presently claimed method or apparatus for ***sealing*** a fluid sample collection device. That is, one of the clear steps of the claimed invention is the sealing of the fluid entry orifice, which simply has no relevance to the "open" pads of Yakota. Accordingly, Applicants respectfully assert that it is improper to combine Zelin with Yakota, and for this reason also, request the withdrawal of this rejection.

2. Rejection over Davis et al.

Davis et al. initially published on September 11, 2003 as US2003/0170881. The present application was filed before this date on September 10, 2003. Thus, Davis et al. was not published or patented before the date of the invention of the present application and cannot qualify under 35 U.S.C. § 102(a). Thus, Davis et al. only constitutes prior art, if at all, under 35 USC §102(e). Also Davis et al. was not published or patented one year before the earliest U.S. filing date of the present application and cannot qualify under 35 U.S.C. § 102(b).

The present application, U.S. App. No. 10/658,528, and U.S. Patent No. 7,419,821 were, at the time the invention of the present application was made, owned by the same person or subject to an obligation of assignment to the same person (specifically, i-Stat Corporation, now Abbott Point of Care Inc.), as defined under 35 USC §103(c)(1). Davis et al. is thus disqualified as a citable reference under 35 U.S.C. § 103(c)(1), and the withdrawal of this rejection is respectfully requested.

3. Dependent Claims

Dependent claims 2-4 and 6-24 and 63-64 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable for the reasons set forth in the Office Action. These claims depend variously from independent Claims 1 and 5, respectively. Accordingly, these claims incorporate the features of independent Claim 1 or Claim 5 and are patentable over the cited references for at least the same reasons as independent Claims 1 and 5.

E. Conclusion

For the foregoing reasons, the allowance of pending Claims 1-24, 63 and 64 is respectfully requested. Should the Examiner have any questions regarding this response or the application in general, the Examiner is urged to contact the Applicants' attorney, Justin L. Krieger, by telephone at (202) 625-3858.

All correspondence should continue to be directed to the address given below.

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